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Clinical Conversations in HIV-Associated Wasting

A brief discussion with Anthony Jones, MD

INDICATIONS AND USAGE

Serostim® (somatropin) for injection is indicated for the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance. Concomitant antiretroviral therapy is necessary.

IMPORTANT RISK INFORMATION

CONTRAINDICATIONS

Serostim® should not be used in patients with acute critical illness, active malignancy, hypersensitivity to somatropin or any of its excipients, or diabetic retinopathy. Increased mortality has been reported in patients with acute critical illness due to complications following surgery, multiple accidental trauma, or acute respiratory failure. Preexisting malignancies should be inactive and treatment completed prior to instituting therapy. Serostim® should be discontinued if there is evidence of tumor recurrence. Systemic hypersensitivity reactions have been reported with postmarketing use of somatropin products.

Please see additional Important Risk Information throughout and enclosed Full Prescribing Information.



Serostim[®]
(somatropin) for injection

A brief discussion with Anthony Jones, MD

Q: What led you to specialize in HIV care?

A: When I was in medical school in Seattle, many of my patients were men in their 20s and 30s with pneumonia, meningitis, or dementia. These should have been healthy young men, but they were being ravaged with serious illnesses and dying. It was disturbing. I felt like I had to do something to make a difference.

When I came back to California for residency, I continued to have encounters with AIDS patients. I did prenatal care and delivered babies for a while, and took care of pregnant HIV-positive women. I remember the social stigma and the political lack of concern for people who were being negatively impacted by their diagnosis. As I matured professionally and better understood the relationship between these factors and health, I became more galvanized.

Certainly as years have gone on, I feel that I have become a voice for this patient population, and the rewards and the relationships have been irreplaceable. Now, it's a big part of what I look forward to in medicine every day.

Q: How do you evaluate patients for HIV-associated wasting?

A: I begin by looking at the vitals in my patients' charts when they come in for a visit. I look at the trends in their weight and BMI. I also ask general, open-ended questions. For example, "How are you doing with your medications?" These can help me determine if they are comfortable with their ARVs. I ask about their nutrition and food intake, and whether they feel successful in attempts to gain or maintain their weight. I also inquire about energy level and endurance.

If a patient is experiencing unintentional weight loss and loss of energy, I start by looking at their overall situation and condition. I will screen them for other potential underlying issues that are associated with weight loss and malnutrition, and make sure they are compliant with their antiretroviral therapy.

Q: Can you tell us about a patient you've treated with Serostim® (somatropin) for injection?

A: Recently I treated a man who is now in his early 40s. He was diagnosed with HIV about 10 to 15 years ago. He had been off his ARVs and had a gradual decline in his weight. He really put himself behind the eight ball, just from a general perspective, and promptly got hospitalized. He had a horrible case of esophageal candidiasis. He had lost a lot of weight and weighed about 85 pounds total. His baseline had been in the 130s. He eventually recovered from the infection and continued his ARV regimen but he never seemed to fully make it back to his baseline weight and energy level.

Q: What triggered your concern that he might have HIV-associated wasting?

A: He's a smaller man, but he was really skin and bones. He was much smaller than he had ever been. He said he was unhappy with his low weight, noting that his clothes used to fit and now were hanging off. That was distressing to him. His energy was low; he had previously liked to be active in his church and sing in the choir, but he stopped doing those things.

It had been a while since he was hospitalized. He had an undetectable viral load, yet he had remained withdrawn in his activities and had really cut back. What called my attention to the fact that he might have HIV-associated wasting was the fact that he was not gaining his muscle mass back and I noticed on his vitals that he was not recovering and regaining his lost weight. To me, that indicated that it was time to intervene.

Q: What did you decide to do?

A: At that point, we started him on an appetite stimulant. He had a little bit of success in terms of weight gain, but it did not get him back to his baseline—nor did it increase his activities to the point that he was back to his original energy levels. He said he had a decent appetite and was eating well, but he wasn't gaining weight.

We also looked into GI issues. He only had some mild diarrhea. He had no problems with swallowing and his acute infection had been resolved months ago. After ruling out potential contributing factors, we had a conversation about other options, Serostim® being one of those options.

If I think a person might be a candidate for Serostim®, I will have a conversation with them about the benefits and side effects of therapy. I draw a little grid that explains the different treatment options so they see why I prefer Serostim® for patients who meet the requirements.

Q: Was that when the patient started treatment with Serostim®?

A: Initially, we had some issues getting insurance approval for Serostim®, and had to go through an appeal. The AXIS Center®, a patient resource provided by EMD Serono, was instrumental in helping the patient to navigate the insurance process.

Q: How would you describe the AXIS Center® to someone who has never utilized it before?

A: From my experience, the AXIS Center® has knowledge about insurance coverage requirements. It was instrumental in helping navigate insurance issues that this patient had. The AXIS Center® also provided patient support. A product support specialist answered all of my patient's questions and arranged in-home injection training at his mother's house, where he received additional Serostim® education.

Q: What was the outcome of Serostim® treatment for this patient?

A: Because of Serostim®, this patient gained weight, had increased energy, had more enjoyment in eating, felt positive changes in his appearance, and reported improvements in how he felt.

Patient Case

Clinician's observation: "I'll ask about nutrition and food intake and whether they feel successful in attempts to gain or maintain their weight. I also inquire about energy level and endurance."

PATIENT PROFILE

40-year-old male on and off antiretroviral therapy since HIV diagnosis in 2005. Patient experienced an episode of esophageal candidiasis and as a result, had significant weight loss. After resuming antiretroviral therapy, he was unable to regain the weight and lean body mass he had lost, and his energy level continued to drop. He reported feeling depressed due to the change in his physical appearance and limitations due to fatigue. Patient was prescribed THC and appetite stimulants. Based on the patient's inability to gain a satisfactory amount of weight, Serostim® (somatropin) for injection was initiated for HIV-associated wasting.

RELEVANT MEDICAL HISTORY

- HIV+ (2005)
- Esophageal candidiasis; adequately treated

SOCIAL HISTORY

- Occupation: Currently unemployed
- Enjoys walking dog and singing in church choir
- History of alcohol abuse

OVERVIEW OF SYMPTOMS AT TIME OF HIV-ASSOCIATED WASTING DIAGNOSIS

- Appeared thin and malnourished
- Clothing fit loosely
- Significant weight loss
- Inability to gain muscle mass
- Withdrawn from usual social activities
- Depression, mostly due to appearance
- Poor appetite
- Mild diarrhea

WEIGHT HISTORY

- Height: 5'6"
- Premorbid weight: 130 lb
- Premorbid BMI: 21
- Weight at HIV-associated wasting diagnosis: 106.5 lb
- BMI at HIV-associated wasting diagnosis: 17.2

PHYSICAL EXAM

- No signs of dysphagia, obstruction, or oral infection

LABORATORY RESULTS

- CD4-cell count: 220 cells/mm³
- Viral load: Undetectable
- Testosterone levels: Within normal range

TREATMENT HISTORY

- THC
- Medical nutrition therapy
- Appetite stimulants

This case study represents a real patient of Dr. Jones, however, it may not be a complete representation of the individual's entire medical case or include his full experience with Serostim®. Certain details such as concomitant medications, dose adjustments, and adverse reactions may not be reflected. For more information obtained from clinical trials and unsolicited post-marketing reporting of adverse experiences, refer to the Important Risk Information throughout and see enclosed Full Prescribing Information.

IMPORTANT RISK INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS

Acute Critical Illness: Increased mortality in patients with acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure has been reported after treatment with [pharmacologic amounts of] somatropin.

Concomitant Antiretroviral Therapy: Somatropin has been shown to potentiate HIV replication in vitro, however there was no increase in virus production when antiretroviral agents were added to the culture medium. All patients received antiretroviral therapy for the duration of treatment during Serostim® clinical trials and no significant increase in viral burden was observed.

Neoplasms: Patients with preexisting tumors should be monitored for progression or reoccurrence. Monitor patients on somatropin therapy carefully for preexisting nevi.

Please see additional Important Risk Information continued on the back and enclosed Full Prescribing Information.

Treatment of HIV-associated wasting should include setting goals and tracking outcomes

Setting treatment goals for your patients and monitoring progress should be part of their follow-up visits. Methods for monitoring and assessing whether patients reach treatment goals:

- Addressing the underlying issues that may be contributing to weight loss
- Evaluating physical endurance
- Measuring weight
- Calculating BMI
- Visually examining physical appearance
- Assessing patient-reported outcomes

Tracking treatment outcomes and assessing whether goals have been met are central to treating HIV-associated wasting.

IMPORTANT RISK INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS

Impaired Glucose Tolerance/Diabetes: Cases of new onset impaired glucose tolerance, new onset type 2 diabetes, and exacerbation of preexisting diabetes have been reported in patients receiving Serostim® (somatropin) for injection. Some patients developed diabetic ketoacidosis and diabetic coma. Patients with risk factors for hyperglycemia and glucose intolerance should be monitored closely and those using antidiabetic agents may require dose adjustment.

Intracranial Hypertension: Intracranial hypertension (IH) with papilledema, visual changes, headache, nausea, and/or vomiting has been reported. Funduscopic examination should be performed prior to initiating treatment with Serostim® and periodically during the course of treatment. If papilledema is observed, treatment should be stopped and restarted at a lower dose after IH-associated symptoms have resolved.

Severe Hypersensitivity: Serious systemic hypersensitivity reactions including anaphylactic reactions and angioedema have been reported with postmarketing use of somatropin products. Patients and caregivers should be informed that such reactions are possible and that prompt medical attention should be sought if an allergic reaction occurs.

Fluid Retention/Carpal Tunnel Syndrome: Swelling (particularly in the hands and feet), musculoskeletal discomfort, or carpal tunnel syndrome may occur during treatment with Serostim®. Symptoms may resolve spontaneously, with analgesic therapy, or after reducing the frequency of dosing. If symptoms of carpal tunnel do not resolve by decreasing the weekly number of doses, it is recommended that Serostim® treatment be discontinued.

Skin Atrophy: Rotate the injection site to avoid tissue atrophy.

Pancreatitis: Cases of pancreatitis have been reported rarely. Consider pancreatitis in patients who develop persistent severe abdominal pain.

ADVERSE REACTIONS

In clinical trials in HIV-associated wasting or cachexia the most common adverse reactions (incidence >10%) were increased tissue turgor, arthralgia, myalgia, and arthrosis, which may be responsive to dose reduction. Other common adverse reactions (incidence >5%) included nausea, fatigue, gynecomastia, paresthesia, generalized edema and hypoesthesia.

SPECIAL POPULATIONS:

Somatropin should be used during pregnancy only if clearly needed and with caution in nursing mothers because it is not known whether somatropin is excreted in human milk. The safety and effectiveness of somatropin in patients with hepatic or renal impairment or in patients aged 65 years and over have not been evaluated in clinical studies.

Please see the enclosed Prescribing Information for full disclosure.



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